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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,557	04/01/2004	Ronald M. Jones	52325-8019.US00	1236

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PERKINS COIE LLP
P.O. BOX 2168
MENLO PARK, CA 94026

EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 08/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/816,557	JONES, RONALD M.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *2-4 and 15-31* is/are allowed.

6)☒ Claim(s) *1 and 5-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1 and 5-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Jones et al (US 2003/0224471).

Jones et al teach of a high density lipoprotein (HDL) assay device and method for measuring the concentration of HDL-associated cholesterol in a blood fluid sample. The device comprises a main body or support 15, which defines a well 16 sized to receive a quantity of blood. The well is in contact with a sieving pad 22 that is carried in a notched region 20 formed in the upper edge of the support. A capillary conduit 18 may connect the well 16 to the sieving pad 22. Sieving pad 22 functions to partially remove large particulate matter such as blood cells as the sample migrates through the pad matrix in a bottom-to-top direction. The sieving pad 22 in turn contacts an elongate strip or sample distribution matrix 26, which extends along the upper edge of the plate 15. Matrix 26 serves to distribute the sample from a central application region 28, which is in contact with the pad 22, to sample collection regions 30, 32 within the matrix. The device also includes a reaction bar 60 composed of an elongate support 62, and multiple wettable absorbent reaction test pads 64, 66, 68 and 70 carried on the lower surface of the support. Each test pad contains analyte-dependent reagents effective to produce an analyte-dependent change in the pad. One of the test pads is an HDL test pad 64 that contains reagents that react with HDL so as to detect the HDL. The HDL can be detected optically, or the HDL

test pad can be a biosensor that electrochemically measures the production of oxygen or hydrogen peroxide. See paragraph nos. 0068-0069 in Jones et al. Some or all of the test pads are asymmetric membranes having a porosity gradient across the thickness of the membrane. The reaction bar is mounted on a support 15 by mounting means effective to maintain the device in either a sample-distribution position where the test pads and a reagent pad are spaced apart from the sample distribution matrix or a test position, where the test pads and reagent pad are in fluid communication with the sample distribution matrix. The mounting means can be used to break fluid communication between the sample distribution matrix and the test pads after a desired amount of sample has entered the pads or after a predetermined contact time. The mounting means can include a pair of resilient members such as elastomeric blocks 71, 72. Upstream of the HDL test pad is a reagent pad 74 having immobilized therein a polyanionic reagent effective to bind and remove from the fluid sample non-HDL lipoproteins. The reagent pad 74 is located between the sample distribution matrix and the HDL test pad. The reagent pad 74 can be attached to the HDL test pad, as depicted in Figure 1. See paragraph nos. 0048-0059 in Jones et al. The polyanionic reagent in the reagent pad selectively removes LDL and VLDL particles from the fluid sample, and is preferably a sulfonated polysaccharide. The reagent pad 74 effectively traps non-HDL lipoproteins within the pad and prevents them from entering the HDL pad 64. In one embodiment, the reagent pad 74 consists of a single membrane, but in other embodiments, multiple stacked membranes may be used. The HDL test pad can be formed from a polysulfone membrane impregnated with reagents that detect HDL. The HDL test pad 64 can also be laminated to the reagent pad 74 before the application of reagents, and the respective

reagents are then applied, first to one side of the laminate and then to the other. See paragraph nos. 0088-0089 in Jones et al.

3. Claims 1 and 5-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Jones et al (US 2003/0166291, now US Patent no. 6,881,581).

Jones et al teach of a high density lipoprotein (HDL) assay device and method for measuring the concentration of HDL-associated cholesterol in a blood fluid sample. The device comprises a main body or support 15, which defines a well 16 sized to receive a quantity of blood. The well is in contact with a sieving pad 22 that is carried in a notched region 20 formed in the upper edge of the support. A capillary conduit 18 may connect the well 16 to the sieving pad 22. Sieving pad 22 functions to partially remove large particulate matter such as blood cells as the sample migrates through the pad matrix in a bottom-to-top direction. The sieving pad 22 in turn contacts an elongate strip or sample distribution matrix 26, which extends along the upper edge of the plate 15. Matrix 26 serves to distribute the sample from a central application region 28, which is in contact with the pad 22, to sample collection regions 30, 32 within the matrix. The device also includes a reaction bar 60 composed of an elongate support 62, and multiple wettable absorbent reaction test pads 64, 66, 68 and 70 carried on the lower surface of the support. Each test pad contains analyte-dependent reagents effective to produce an analyte-dependent change in the pad. One of the test pads is an HDL test pad 64 that contains reagents that react with HDL so as to detect the HDL. The HDL can be detected optically, or the HDL test pad can be a biosensor that electrochemically measures the production of oxygen or hydrogen peroxide. See paragraph nos. 0072-0076 in Jones et al. Some or all of the test pads are asymmetric membranes having a porosity gradient across the thickness of the membrane. The

reaction bar is mounted on a support 15 by mounting means effective to maintain the device in either a sample-distribution position where the test pads and a reagent pad are spaced apart from the sample distribution matrix or a test position, where the test pads and reagent pad are in fluid communication with the sample distribution matrix. The mounting means can be used to break fluid communication between the sample distribution matrix and the test pads after a desired amount of sample has entered the pads or after a predetermined contact time. The mounting means can include a pair of resilient members such as elastomeric blocks 71, 72. Upstream of the HDL test pad is a reagent pad 74 having immobilized therein a polyanionic reagent effective to bind and remove from the fluid sample non-HDL lipoproteins. The reagent pad 74 is located between the sample distribution matrix and the HDL test pad. The reagent pad 74 can be attached to the HDL test pad in permanent contact, as depicted in Figure 1. See paragraph nos. 0050-0065 in Jones et al. The polyanionic reagent in the reagent pad selectively removes LDL and VLDL particles from the fluid sample, and is preferably a sulfonated polysaccharide. The reagent pad 74 effectively traps non-HDL lipoproteins within the pad and prevents them from entering the HDL pad 64. The asymmetric membrane of the reagent pad 74 is preferably oriented with its larger pored surface facing the sample distribution matrix 26, and its smaller pored surface facing and contacting the HDL test pad 64. This orientation allows free access of sample into the reagent pad through the larger pores, and prevents passage of precipitated material, formed as the sample contacts the precipitating agent in the reagent pad, through the smaller pores. See paragraph no. 0066 in Jones et al. In addition, the asymmetric membrane employed as the HDL test pad is oriented with its smaller pored surface facing upward and its larger pored surface facing reagent pad 74. See paragraph no. 0068 in Jones et al. In one

embodiment, the reagent pad 74 consists of a single membrane, but in other embodiments, multiple stacked membranes may be used. See paragraph no. 0067 in Jones et al. The HDL test pad can be formed from a polysulfone membrane impregnated with reagents that detect HDL. The HDL test pad 64 can also be laminated to the reagent pad 74 after the application of reagents. See Figure 3 and claim 19 in Jones et al.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1 and 5-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 8, 10 and 13-16 of U.S. Patent No. 6,881,581. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite an assay device for measuring serum cholesterol associated with high density lipoproteins (HDL) in a blood fluid sample also containing lipoproteins other than HDL such as low density lipoprotein (LDL) and very low density lipoprotein (VLDL) comprising a sample distribution matrix effective to distribute a blood fluid sample from a sample application region to one or more sample collection regions, a HDL test pad in which HDL concentration can be assayed spaced apart from the sample distribution matrix, a reagent pad containing a reagent to selectively bind and remove non-HDLs

from the sample, wherein and the HDL test pad and reagent pad are joined together or attached to one another, and a mounting means that is effective to maintain the device in a sample distribution position, wherein the HDL test pad and reagent pad are spaced apart from the sample distribution matrix, and to transfer the device to a test position, whereby the HDL test pad and reagent pad are in contact with the matrix.

6. Claims 1 and 5-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-10 and 12-14 of copending Application No. 10/410,671 (corresponding to publication no. US 2003/0224471). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite an assay device for measuring serum cholesterol associated with high density lipoproteins (HDL) in a blood fluid sample also containing lipoproteins other than HDL such as low density lipoprotein (LDL) and very low density lipoprotein (VLDL) comprising a sample distribution matrix effective to distribute a blood fluid sample from a sample application region to one or more sample collection regions, a HDL test pad in which HDL concentration can be assayed spaced apart from the sample distribution matrix, a reagent pad containing a reagent to selectively bind and remove non-HDLs from the sample, wherein and the HDL test pad and reagent pad are joined together or attached to one another, and a mounting means that is effective to maintain the device in a sample distribution position, wherein the HDL test pad and reagent pad are spaced apart from the sample distribution matrix, and to transfer the device to a test position, whereby the HDL test pad and reagent pad are in contact with the matrix.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 2-4 and 15-31 are allowable over the prior art of record since none of this prior art of record teaches or fairly suggests a method for preparing a device suitable for measuring serum cholesterol that comprises providing a reagent pad either coated with an acrylic acid copolymer or formed of an asymmetric polysulfone membrane having a small pore side and an open pore side and containing a reagent effective to selectively bind and remove non-HDLs from a fluid sample, applying a HDL test pad containing HDL test reagents therein to the reagent pad, and heating to adhere the reagent pad and the HDL test pad together.

8. Applicant's arguments filed June 14, 2005 have been fully considered but they are not persuasive.

The previous rejections of the claims under 35 USC 112, second paragraph made in the last Office action mailed on March 14, 2005 have been withdrawn in view of Applicant's amendments to the claims.

The declaration under 37 CFR 1.132 filed June 14, 2005 is insufficient to overcome the rejection of claims 1 and 5-14 based upon Jones et al (US 2003/0224471) and Jones et al (US 2003/0166291, now US Patent no. 6,881,581) as set forth in the last Office action because a declaration under 37 CFR 1.132 cannot be used to overcome a rejection made under 35 USC 102(e) based upon a patent or US publication that claims the same invention (i.e. one that is not patentably distinct) as the invention recited in the instant claims. A declaration filed under 37 CFR 1.132 can only be used to overcome a rejection made under 35 USC 102(e) that is based upon a patent or US publication that discloses the same or similar invention as recited in the

instant claims (i.e. discloses the same or similar invention in the specification portion of the patent or publication). See MPEP 716.10. Since the claims in both Jones et al (US 2003/0224471) and Jones et al (US 2003/0166291, now US Patent no. 6,881,581) recite versions of the invention recited in instant claims 1 and 5-14 that are not patentably distinct from one another, the declaration filed under 37 CFR 1.132 is not persuasive to overcome the 35 USC 102(e) rejection of claims 1 and 5-14 as being anticipated by both Jones et al (US 2003/0224471) and Jones et al (US 2003/0166291, now US Patent no. 6,881,581). However, the declaration filed under 37 CFR 1.132 is persuasive in overcoming the rejection of claims 23-30 under 35 USC 102(e) as being anticipated by both Jones et al (US 2003/0224471) and Jones et al (US 2003/0166291, now US Patent no. 6,881,581) since both of these patents or publications include claims to a method for measuring serum cholesterol associated with HDL in a blood fluid sample that are patentably distinct from instant claims 23-30. In addition, the declaration filed under 37 CFR 1.132 is persuasive in overcoming the rejection of claims 2-4 and 15-22 under 35 USC 103 since neither patent or publication to Jones et al includes claims to a method for preparing a device suitable for measuring serum cholesterol as recited in instant claims 2-4 and 15-22.

Applicant's amendments to claim 1 necessitated the new obviousness-type double patenting rejections, and therefore, this Office action is being made final.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

August 23, 2005

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP [redacted] 1700